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Sarath K. Ganji
The Hebrew University of Jerusalem

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SARATH K. GANJI
The Hebrew University of Jerusalem
Anna Sobol Levy Fellow in the Rothberg International School's Islamic and Middle Eastern Studies Program

In both the economic and political realm, India and Brazil exhibit similar interests and policies. Yet, in the area of intellectual property rights (IPRs)—in particular, generic production of antiretroviral drugs to treat HIV/AIDS—these nations' policies differ. India, for example, has exercised a policy of strategic cooperation with the United States and pharmaceutical companies, while Brazil has pursued a policy of strategic restraint. Why is this so? These differing approaches can be attributed to the manner in which these two nations initially implemented the defining IPR agreement, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). India's gradual implementation of TRIPS afforded it the opportunity to modify the agreement so as to preserve its generic manufacturing sector. In contrast, Brazil's hurried implementation significantly restricted the state's generic manufacturing sector, in turn motivating the state to pursue a more adversarial approach with the United States and pharmaceutical companies to safeguard its generic drug sector. By examining India and Brazil's distinct implementation processes of TRIPS, this paper reveals the strengths and weaknesses of each respective policy process, shedding light on the larger policy controversies surroundings IPRs in the developing world.[1]

In early 2006, Gilead Sciences, an American pharmaceutical company, submitted a patent application for its antiretroviral drug (ARV) Viread to the Indian government. The drug, a second-line therapy widely distributed in developed countries (DCs), such as the United States and Europe, was prohibitively expensive in lesser-developed countries (LDCs), thus preventing its distribution to those populations (Gentleman and Kumar 2006). Opposition to the patent request from civil society groups and humanitarian organizations was tremendous, as they demanded that the Indian government refuse it. Patent protection was ultimately granted to Gilead. To cement relations with the government, however, the firm partnered with several of India's generic pharmaceutical manufacturers, allowing them to produce and distribute the drug

[1] Author can be contacted at proskq@gmail.com

so long as national and international regulatory standards were followed and a 5 percent royalty was paid (Gilead Sciences 2006; Singh 2009). The disagreement, it appears, ended amicably.

Brazil's approach to pharmaceutical companies is far less genial. In 2001 – against the wishes of the United States—Brazil threatened to break a patent on the first-line drug Nelfinavir produced by Roche. According to Brazil, the firm was initially unwilling to negotiate a reduced price for the drug, which constituted over one-quarter of the government's total spending on ARVs (Galvao 2002: 1864). The government's threat to permit state manufacturer Far-Manguinhos to produce the drug locally motivated price concessions from Roche, thus settling the dispute. Even so, the United States took up the pharmaceutical's cause, filing a complaint with the World Trade Organization (WTO). The complaint was eventually dropped, but U.S.-Brazilian relations, in the area of intellectual property rights (IPRs), have since remained on rocky ground (Champ and Attaran 2002: 365-366).

India and Brazil's differing approaches to ARV access are remarkable, given how similar the economic and political conditions guiding their behavior actually are. Both nations enjoy rapid economic growth characteristic of their "BRIC" status, exercise sizeable influence in global events and institutions, and possess well-developed manufacturing sectors for pharmaceutical products. And yet, their approaches to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are very different. India, for example, pursues a policy of strategic cooperation with the West, complying with intellectual property directives in a piecemeal manner that corresponds with TRIPS's compliance schedule, also known as "transition periods." Brazil, on the other hand, favors a policy of strategic competition, readily threatening the use of and issuing compulsory licenses to satisfy its domestic ARV demand. In other words, as much as these nations share in common, India appears to use different TRIPS flexibilities than Brazil in its efforts to balance domestic public health objectives and international IPR standards. Why is this so?

Underlying these nations' preferences for using different TRIPS flexibilities—in particular, transition periods for India and compulsory licensing for Brazil—is their unique policy responses to economic coercion by Western nations. Although both nations' histories are characterized by economic protectionism and weak intellectual property standards, their sudden emergence in global affairs quickly integrated them into the global economy, in turn exposing them to Western economic pressures through trade sanctions. U.S. pressure against India and

Brazil in the late 1980s demonstrates how effective economic coercion can be. In the case of the TRIPS Agreement, however, India reacted to Western pressures by implementing the agreement in a gradual fashion, whereas Brazil hurriedly enacted it. As a result, India's legal system was better positioned to deal with new global patent laws than Brazil's, which instead exercised its own brand of economic coercion—threat or use of compulsory licensing—to retrieve ground previously lost when it first ratified TRIPS. As such, this paper compares India's and Brazil's distinct approaches to TRIPS implementation, revealing their strengths and weaknesses and, in turn, possible ways for non-Western states to reconcile the demands of global economic integration with the imperatives of domestic health policy.

Support for this argument unfolds in three parts. First, a discussion of the WTO's TRIPS Agreement is provided, noting the key TRIPS provisions and amendments that relate to public health and the flexibilities established to ensure protection of member states' health objectives. An overview of India and Brazil's legislative approaches to TRIPS implementation is included as well. Second, the Indian and Brazilian strategies for dealing with TRIPS provisions are examined. Prior to exploring their particular strategies, a discussion of their differing public health goals is presented to familiarize the reader with each country's unique HIV/AIDS burdens. Upon noting these differences, India and Brazil's respective implementation processes are discussed, with particular attention to the ways in which outside actors—the United States for India and name-brand pharmaceutical companies for Brazil—interacted with and influenced each policy process. Finally, policy recommendations are given concerning how LDCs should approach IPR legislation and, in particular, TRIPS.

Reconciling Public Health with the TRIPS Regime

The TRIPS Agreement represents one of the most contentious aspects of North-South relations. In addition to the previously cited cases involving India and Brazil, major legal disputes pitting governments against pharmaceutical companies took place in Thailand, South Africa, and the Philippines, garnering much international attention and controversy (Osewew, Nkrumah, and Sackey 2008: 1-2; Ford et al. 2007: S21-S29; Oxfam International 2006). Civil society groups have played a particularly important role in these matters, vocalizing their opposition to what they perceive as Western and corporate interests superseding public health priorities. Cecelia Oh of the Third World Network contends that "the TRIPS Agreement does not

adequately take into account public health needs." She notes that the agreement is often described as a "charter of rights for patent holders," which ignores the "interests of the consumers and patients" (Oh 2000). Such sentiments reflect the atmosphere of frustration and anger that underlies the protests and petitions found in many developing nations today.

At the center of these disputes is the struggle to balance the benefits of IPRs, such as patent protection to fuel innovation, with the priorities of public health, such as providing inexpensive ARVs to patients. According to the World Intellectual Property Organization (WIPO), a patent is a "title of legal protection of an invention, issued, upon application and subject to meeting legal criteria, by a government office" (WIPO 2008: 8.1.18). For pharmaceutical companies, the exclusive right provided by patents to produce and distribute a good allows them to recoup the funds spent on research and development for that particular good. This is the case because patents create temporary monopolies that permit companies to set their own market prices (Smith, Correa, and Oh 2009: 685-686). The absence of patents, it is argued, jeopardizes the innovation of new medicines as well as the profitability and, in turn, sustainability of pharmaceutical companies. This was the primary reason pharmaceutical companies urged Western nations to bring LDCs into a global IPR regime, as they "complained of commercial losses due to the weakness of intellectual property rights protection in most of the newly industrializing countries" (Velasquez and Boulet 1997: 15).

Complicating this issue is the globalization of goods and services, which has made IPR standards all the more difficult to set and enforce. IPRs are hardly new and in fact are codified in legal documents throughout the developing world that arose as early as the nineteenth century. Yet, the rise of generic manufacturers in LDCs and increasing ease with which ARVs are exported to other locations undermine pharmaceutical companies' traditional model of drug development. At the forefront of this transformation in drug development and distribution are India and Brazil, whose thriving domestic pharmaceutical industries are of concern to major pharmaceutical companies. To appreciate India and Brazil's specific IPR policies, however, it is necessary to understand the evolving importance of health as represented in international events and disputes surrounding IPRs.

A New Vision for IPRs

The culmination of the Uruguay Round of Trade Negotiations in 1994 represented a watershed moment in international trade relations. Prior to the talks, global trade was largely governed by the General Agreement on Tariffs and Trade (GATT), lacked any provisions specific to IPRs, and found adherents to international trade laws in only a small group of countries (Velasquez and Boulet 1997: 10-11; Hudec 1971: 1299-1300; Drahos 1995: 7-9; Matthews 2004). With the successful conclusion of the Uruguay Round, the World Trade Organization (WTO) was established—an international institution informing policies in over 120 member states (now 153) by establishing rules concerning trade of goods and services, respect for IPRs, and mechanisms for resolving disputes and reviewing members' trade policies (WTO 2007: 23-24). The overarching point of these rules was the promotion of nondiscrimination in trade among member states (most-favored-nation, MFN) and between local and foreign producers (national treatment) (WTO 2007: 10-11).

A key sub-agreement arising from the Uruguay Round was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The purpose of TRIPS is to set global standards for IPRs largely under the purview of national jurisdictions in decades past. Article 7 of the TRIPS Agreement articulates this vision as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations (WTO 1994: Art. 7).

The general vision of knowledge protection expressed by Article 7 frames the agreement's more specific focus on standardization and enforcement of IPR laws (Velasquez and Boulet 1997: 17). Regarding the standardization of IPR laws, Article 2 of TRIPS makes mention of previous IPR conventions, including Berne (1886), Paris (1896), and Rome (1928), as well as the Treaty of Intellectual Property in Respect of Integrated Circuits (1989) (WTO 1994: Art. 2, Pt. 1). In applying these conventions henceforth to all member states, the WTO not only created a standard set of rules for states to follow but also grounded it in the history of IPR development. Regarding the enforcement of IPR laws, Part III of the agreement lays out the obligations of states "to permit effective action against any act of infringement of intellectual property rights" (WTO 1994: Art. 41, Pt. 3). Articles 42-50 entrust enforcement to local judicial institutions,

while Articles 63-64 set up the Council of TRIPS to handle dispute prevention and settlement matters (WTO 1994: Pts. 3 and 5; Lehman 2003). As its enforcement provisions indicate, TRIPS seeks protection of IPRs by layering the legal processes meant to govern them, nesting domestic regulatory institutions within an international regulatory framework. Furthermore, these processes fit within the broader vision of the WTO by applying the principles of MFN and national treatment to IPRs.

Delving deeper into TRIPS's standardization and enforcement policies, the agreement hinges on four key provisions. First, member states must make patents available for "any inventions, whether a product or process, in all fields of technology," provided that they are new, non-obvious, and useful (WTO 1994: Art. 27, Pt. 1). This provision has a particular bearing on developing nations, who previously exempted all product inventions and certain fields, such as pharmaceuticals, from patent protection (Cullet 2003: 141; Coriat, Orsi, and d'Almeida 2006: 1037). Second, patent holders receive exclusive rights to their inventions, requiring other entities to seek their permission before pursuing the selling or importing of patented goods (WTO 1994: Art. 28, Pt. 1). Third, patents are uniformly protected for a period of twenty years (WTO 1994: Art. 31, Pt. 1). And fourth, for situations in which a process patent holder accuses another entity of duplicating its invention, the burden of proof falls on the accused to demonstrate the uniqueness of its creation (WTO 1994: Art. 34, Pt. 1). As with the first provision mentioned above, this measure appears directed at LDCs, since their previous allowance of process patents was subject to weak enforcement laws. The sum of these provisions forms the basis of TRIPS and is ultimately responsible for the controversies following conclusion of the Uruguay Round.

TRIPS Amendments

Initial LDC reservations to TRIPS during the Uruguay Round erupted into full-scale opposition following its conclusion. Civil society groups and local populations, in particular, argued that TRIPS constrained LDCs' actions in the area of public health. According to Steve Lohr of *The New York Times*, "The concern about [TRIPS] is that it is too much of a one-size-fits-all approach that works to the detriment of developing countries" (Lohr 2002). Such opposition, emanating from both the developed and developing worlds, subsequently motivated concessions from DCs that dominated global trade relations over the next decade.

Yet, as much as TRIPS is criticized by human rights groups and LDCs, it is important to note the exception clauses of TRIPS—what are often referred to as flexibilities—which enable LDCs to comply more easily with the agreement's provisions. Two flexibilities are of particular importance to this study. The first flexibility is the transition period for compliance given to states, permitting them to adopt the agreement in a piecemeal fashion. The first transition period took place from 1995-2000, requiring states to extend legal protection to both product and process patents and to recognize the twenty-year duration of patents. The second period, lasting from 2000-2005, focused on extension of TRIPS to all fields, including pharmaceuticals and agrochemicals, and employment of a "mailbox" system to store patent applications yet considered for approval. The final period ends in 2016 and is primarily the result of the Doha Declaration, which articulated the importance of public health to LDCs (Musungu and Oh 2006: 12-14).

The second flexibility is states' use of compulsory licenses, as outlined in Article 31 of the agreement. Compulsory licenses permit states, by law, "to grant a license, without permission from the holder, on various grounds of general interest," including "absence of working, public health, economic development, and national defense" (Velasquez and Boulet 1997: 43). In the area of pharmaceuticals, for example, a state may issue a license granting production and/or distribution authority for a drug to a generic manufacturer, effectively breaking the patent holder's monopoly on the good. The World Health Organization (WHO) notes the potential advantages of this flexibility for public health measures, stating that compulsory licenses can play a crucial role in "ensuring that patents are able to meet public health needs, and that patent rights do not unnecessarily hinder or prevent access to affordable medicines" (Musungu and Oh 2006: 27-28). Of course, such licenses require the issuing state to compensate the patent holder financially, to limit the scope and duration of the license, to make the license non-exclusive, and to restrict the licensed good to domestic use (WTO 1994: Art. 31, Pt. 1). Important to note is that the threat or use of a compulsory license often entails extensive legal preparatory work, not to mention legal opposition from the patent holder, which increases the costs to states issuing them. Furthermore, compulsory licenses are useful insofar that states have the technological capacity to produce the licensed material, since importation of compulsory licensed goods was prohibited under the original agreement (Coriat, Orsi, and d'Almeida 2006: 1042).

Mounting opposition to the perceived injustices of the IPR regime brought about major amendments to TRIPS in 2001 and 2003. In 2001, a contingent of African states and nongovernmental organizations (NGOs), led by Brazil, brought negotiations at the Doha Ministerial Conference to a halt, seeking clarification on TRIPS's stance toward LDC access to essential medicines. The result was the Doha Declaration on the TRIPS Agreement and Public Health, which stated:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all (WTO 2001).

The declaration recognized the right of states, in matters of public health, to interpret TRIPS provisions broadly, to grant compulsory licenses, and to engage in parallel importation.

Such recognition, however, did little to address the inability of states lacking manufacturing capacity to use compulsory licenses. As a result, a second amendment was concluded in 2003. The Decision of the TRIPS Council, as it was known, affirmed states' ability to export and import pharmaceutical products in exceptional circumstances. More specifically, it required that should a drug-importing nation be an LDC, that it provide the TRIPS Council with details of both its request and the compulsory license, and that the license be subject to limitations (Coriat, Orsi, and d'Almeida 2006: 1046-1047; Barton 2004: 149). Although ignoring other pertinent issues like drug affordability, these amendments nonetheless relieved LDCs' concerns regarding TRIPS's effects on public health policy.

The Implementation Process in India and Brazil

Given the evolving importance of public health to international trade and intellectual property law, this section observes India and Brazil's processes for incorporating the TRIPS provisions into domestic law. India, on the one hand, adopted TRIPS in phases, beginning in 1999 and ending in 2005. Brazil, on the other hand, fully committed to the agreement in 1996. The specific rationale behind these differing strategies is examined later in this paper. In this section, however, knowledge of these nations' IPR legacies and approaches to TRIPS implementation is provided.

India's three-phase approach to TRIPS implementation is tied to its intellectual property tradition of making patents "work for the nation" (Rangnekar 2006: 408). Set during an era when postcolonial ideas motivated the nation's leaders to turn inward as they dealt with economic and political challenges, India's original 1970 Patents Act afforded the nation a great deal of leverage against multinational companies and Western powers. As Dwijen Rangnekar suggests, "These changes to national patent law lie at the heart of building indigenous technological and scientific competency" (Rangnekar 2006: 411). A key provision of the act—and one most pertinent to this study—is that found in Chapter 2, Section 3, which lists those goods that are not patentable, including "any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings" (The Patents Act 1970: Ch. 2, Sec. 3). Other provisions limit patents to processes, provide extensive guidelines for issuing compulsory licenses, and restrict protection to seven or fourteen years, depending on type of invention patented (Rangnekar 2006: 410-411). These measures did much to advance state interests over private ones and, in fact, are credited with shaping India's thriving generic drug manufacturing industry today.

Given such favorable IPR laws for Indian manufacturers, changes to it would be met with controversy domestically. This proved true with the possible implementation of TRIPS. Hence, to alleviate public outrage while complying with U.S. demands, the Indian government implemented TRIPS by amending the Patents Act on three separate occasions. The first occasion, in 1999, was actually initiated in 1994 when the Indian president issued an ordinance granting exclusive marketing rights to patent holders and establishing a mailbox procedure to handle patent applications (Ministry of Law and Justice 1999: 1-5). The ordinance initially failed passage by both houses of Parliament in 1995; however, under U.S. and WTO pressure, the legislation was sent back to Parliament and finally adopted on March 26, 1999 (Ganguli 1999: 279-281).

The second and third amendments, concluded in 2002 and 2005 respectively, brought India into compliance with TRIPS by its 2005 transition period deadline. The second amendment dealt with more specific TRIPS provisions found in Section 5, including the scope of patentable items, the duration of patent protection, the issuing of compulsory licenses, and the shift in burden of proof on the violating party (Ministry of Law and Justice 2002: 1-24). The third amendment concerned the extension of product patents to chemicals, pharmaceuticals, and agricultural goods (Ministry of Law and Justice 2005: 1-18). Although each amendment

substantially eroded India's autonomy over IPRs based on its powers in the 1970 act, this final amendment was particularly controversial. Rajeev Dhavan penned an editorial in a 2004 edition of *The Hindu* in which he argued that the third amendment was "short changing [India's] post-Doha obligations to both its own and the world's poor." He further noted that India was "putting its sovereignty, status, prestige and obligations at risk" by pursuing the agreement (Dhavan 2004). Amid domestic opposition and international concern that India's cheap ARV exports would no longer aid LDCs, the Indian government passed the amendment, signaling a shift in policy benefitting investors over the Indian public.

Much like India, Brazil conceived of IPRs in the context of post-colonial independence and autonomy, fashioning its 1971 Patent Law to exclude the patenting of products and pharmaceuticals processes. Additionally, the rise of Brazil's drug manufacturing industry, again like India, resulted from Brazil's lax IPR standards, which gave the government tremendous power in protecting and developing its infant industries (Orsi et al. 2003: 113-114). However, Brazil's implementation of TRIPS on 15 May 1996, titled the Industrial Property Law, radically altered its IPR policy in a short timeframe. Beyond the basic TRIPS provisions, Brazil's new patent law, influenced by U.S. pressure, actually went further than what is found in TRIPS. Under the new law, the government was required to retroactively provide patent protection to goods not yet available in Brazil but patented in other nations. This measure was particularly harmful to Brazil's national ARV policy—to provide patients with universal access to ARVs—because it prevented generic and government manufacturers from producing and distributing crucial first and second-line therapies that had only recently been released by innovator pharmaceutical companies (Ford et al. 2007: S22-S24).

To address the clear disadvantages of TRIPS implementation, Brazil included a working requirement in its 1996 legislation. According to this requirement, foreign companies possessing a patent issued by the Brazilian government had to manufacture the patented good in Brazil within three years of the patent's issuing ('t Hoen 2002: 32). The measure, enforced through use of compulsory licensing, thus generates some domestic benefit from foreign firms' patents. Additionally, Brazil attempted to shore up its IPR policies by amending its 1996 law to include greater flexibilities. One flexibility, for example, permits Brazil's Drug Regulatory Authority to review patent claims for pharmaceuticals before granting a patent. With government inspection previously absent from the patent review process, this measure provides a key check on the

retroactive patent protection policy mentioned above (Ford et al. 2007: S24). Passage of the 1996 act thus brought Brazil into compliance with TRIPS but at the cost of its autonomy over IPR policy.

Prioritizing Health

In addition to their unique IPR traditions, India and Brazil also possess differing public health goals. India, on the one hand, has struggled to address the HIV/AIDS pandemic, establishing a national policy not too long after the disease first landed on the subcontinent. Its approach, however, has produced inadequate results, requiring the government to implement additional policies and pursue a more targeted approach to the disease. Brazil, on the other hand, pledged in the early 1990s to eliminate the disease through aggressive treatment and prevention efforts. In particular, its treatment program, which includes free distribution of ARVs to infected Brazilians through the nation's public health system, has been touted as a model for dealing with the disease (da Costa 2003). In their efforts to match resources to goals, India and Brazil have pursued differing policies to meet the HIV/AIDS epidemic.

At present, HIV/AIDS presents a formidable challenge to India's public health system (see Appendix 1). Estimates gathered by India's National AIDS Control Organisation (NACO)—created in 1992 for the purpose of centralizing the nation's AIDS efforts—found that in 2006 between two and three million of India's inhabitants were living with AIDS. More specifically, for every one hundred individuals with the disease, sixty-one were males and thirty-nine females (NACO). More disconcerting is that, although the disease burden of southern Indian provinces decreased in recent years, the disease burden in northern and eastern provinces increased (NACO). This coupled with increasing transmission through intravenous drug use and homosexual males has complicated national efforts to address the epidemic.

For a democracy like India, investments in public health are not only a social goal but also a political necessity. The government's response to the disease, however, has not been particularly far-reaching or effective. Specifically, its response has unfolded in phases that have done more to address bureaucratic obstacles to HIV/AIDS action—such as accountability and responsibilities at the state and federal levels—than actual containment of the disease itself. Initially, the Indian government established the National AIDS Control Program (NACP) to monitor the spread of the disease in select areas. By 1991, NACP was expanded to "focus on

blood safety, prevention among high-risk populations, raising awareness in the general population, and improving surveillance" (Mozumder and Nora 2008). It was during the first phase of NACP from 1992-1999 that NACO was created and province-level policies were enacted. The second phase of NACP from 1999 to 2006 saw continued expansion of the program at the provincial level, greater focus on interventions for high risk-groups, and increasing engagement with NGOs for local interventions. A particularly important development was the creation of the State AIDS Control Societies, whose purpose was to link governmental priorities to NGO programs (Mozumder and Nora 2008). The current phase of NACP, though only a few years old, has made strides to partner with civil society organizations to increase its focus on data collection and to include target populations themselves in treatment and prevention programs.

Although these efforts are promising, shortcomings reveal how limited India's efforts have been thus far. At an administrative level, India's government apparatus wields little control over rural communities that rely more on local governments to coordinate public health efforts. Polling shows that women in more rural provinces still have little knowledge of what HIV/AIDS is, though their regions have been particularly hard hit (Mozumder and Nora 2008). At a managerial level, India's institutions lack the capacity to scale up their interventions in affected regions, partly due to bureaucratic bottlenecks and partly to accountability problems. Even at a behavioral level, HIV/AIDS institutions must deal with stigma and discrimination that undermine effective policy interventions (Mitra, Hate, and Shaffer 2007). In these ways, then, India's public health goals are not particularly ambitious, nor are its policies especially effective.

Much like India, Brazil found itself in the midst of a public health crisis in the 1980s, as the incidence of HIV/AIDS soared (see Appendix 2). Using South Africa, a nation deeply affected by HIV/AIDS, as a reference point for disease burden provides a useful comparison. Brazil's disease burden is driven primarily by homosexual transmission and intravenous drug use; in 1990 Brazil had the same prevalence rate as South Africa. Since then, however, Brazil's HIV/AIDS situation has changed dramatically. By 1995 Brazil's incidence rate had declined by 50 percent, whereas South Africa's had increased by 10 percent. (Okie 2006: 1977-1981). Additionally, the World Bank's prediction in the early 1990s that, by 2000, 1.2 million of Brazil's population would be infected with HIV proved incorrect; the actual figure was roughly half that of the prediction (Okie 2006: 1977-1981). According to UNAIDS statistics from 2005,

620,000 individuals live with HIV in Brazil—contraction patterns reflecting increasing rates among women and the general population (UNAIDS 2007: 31).

Brazil's apparent success in addressing the HIV/AIDS epidemic is largely due to its political culture and unique policy approaches. Regarding the former, the end of Brazil's military dictatorship in 1985 inaugurated the nation's human rights-oriented democracy, in which its constitution declared healthcare "a right of all and a duty of the state" (Constitution of Brazil 1988: Art. 196, Sec. 2). The declaration paved the way for later government efforts to distribute ARVs at no cost to the public once clinical trials revealed their effectiveness. Regarding the government's policies and programs, its prevention efforts have targeted high-risk populations, including injecting drug users and commercial sex workers, which have reduced infection rates in both groups (Okie 2006: 1977-1981). Its well-known treatment programs, by ensuring universal ARV treatment to the population, have not only reduced incidence rates but have also fostered a culture of openness in which stigma plays less of a role in hindering HIV infectees to report their status and seek treatment (Okie 2006: 1977-1981). Such broad-based prevention and treatment efforts, coordinated by Brazil's National AIDS Control Program, have done much to alleviate the nation's disease burden and in the process, generate widespread acclaim for its successes.

Comparing India and Brazil's public health priorities and policies, it would seem that differences here would account for differences in their approaches to TRIPS. In the case of India, limited public health goals would make protracted legal battles highly undesirable, especially since the nation already lacks the administrative and managerial powers to aid all citizens afflicted by HIV/AIDS. Hence, the costs of challenging TRIPS outweigh the benefits. In the case of Brazil, its focus on universal ARV treatment—grounded in its 1988 constitution and enforced by the populism of numerous civil society groups—makes its confrontational approach to TRIPS a desirable policy, so much so that the benefits of challenging Western states and pharmaceutical companies outweigh the costs generated by domestic outrage over increased ARV prices. These differing approaches to TRIPS, it would appear, are the product of differing public health goals.

Economic Coercion and TRIPS Implementation

Explaining India and Brazil's diverging IPR policies in terms of public health differences, while appealing, characterizes the policy process as a reaction to domestic priorities

only. Yet, India and Brazil's global economic emergence resulted in greater attention from Western nations, whose economic interests were increasingly affected by the decisions of non-Western states. Thus, a more useful question may be as follows: What about India and Brazil's respective policy processes—as they relate to international actors—has structured their distinct approaches to TRIPS?

Upon examining India and Brazil's IPR policies, one arrives at the following conclusion: India's gradual adoption of TRIPS insulated it from economic coercion by Western states, whereas Brazil's rapid adoption limited its previous policy options, thus forcing it to use compulsory licensing to reclaim its autonomy over IPR policies. Susan Sell acknowledges this outcome when arguing, "The link between U.S. power and the move toward the market by developing countries is the U.S. ability to exploit the vulnerability of targeted states" (Sell 1995: 322). In her analysis, she notes that access to U.S. markets is not only appealing but, in many cases, necessary to the sustainability of targeted economics. The threat of trade retaliation under Section 301 of the 1974 U.S. Trade Act is thus a powerful tool to coerce LDCs to, at minimum, provide the United States with equal access to their markets (Grier 2005; Sell 1995: 322-323). How nations respond to such coercion ultimately shapes which previous policy options they give up and which new policy options they must pursue. Observing India and Brazil's typical reactions to economic coercion, their particular reactions to TRIPS implementation, and examples of patent cases on which there are rulings, one can see just how TRIPS implementation affected these nations' strategic options.

India: Policy Delay and Strategic Cooperation

With greater integration into the global economy comes the expectation to behave according to the norms of the international system. India learned this lesson all too well in its dealings with the West, particularly the United States. Following independence in 1947, India under the leadership of Prime Minister Jawaharlal Nehru and Planning Minister P.C. Mahalanobis adopted a planned mixed economy in which expansion of the public sector and regular state intervention into the private sector served the purposes of limiting India's dependence on imports of foreign capital and exports of commodities and textiles. The protectionist measures that were subsequently implemented came to dominate Indian economic thinking well until the 1980s, when the country's persistent trade deficit motivated a series of

reforms, first by Indira and Rajiv Gandhi and later by Narasimha Rao (Currie 1996: 793-796). Prior to these reforms, however, India's economic fate was of little consequence to the West, especially from the 1960s onward, when India began developing closer economic ties with the Soviet Union (Martin and Kronstadt 2007: 1). Though true that India's initial testing of nuclear weapons in 1974 troubled U.S. policymakers, its nuclear capability drew no overt retaliation from the West, nor did it lead to India's isolation internationally. U.S. interest in and influence over India's economic policies, then, can be traced to the mid-1980s. Indira Gandhi's acceptance of roughly US$3.6 billion in loans from the International Monetary Fund (IMF)—and with it, the expectation of relaxed licensing controls and import restrictions—introduced India to the Washington Consensus. The World Bank and IMF asked much less from India in the way of institutional reforms than it did of many other nations; however, their increased involvement with India, coupled with India's initial economic reform package and subsequent push toward greater economic liberalization, invited greater scrutiny by the West of Indian policies. In the years since, such scrutiny has been particularly focused on India's IPR standards, which have made India the target of Western economic pressure.

A clear example of India succumbing to economic pressure was its initial acquiescence to implementation of the TRIPS Agreement, though it had strong reservations. At the time, India counted the United States as its largest trading partner, depended on it for assistance grants, and was also indebted to the IMF, in which the United States exercised tremendous influence. In the late 1980s, a debt crisis hit the nation, providing the United States with an ideal opportunity to force India's hand in the TRIPS matter. Leveraging its ties to the Indian economy, the United States threatened to halt financial assistance to the nation, going so far as to impose duties on Indian pharmaceutical exports that amounted to US$60 million in losses for Indian companies (Bird 2006:10). India, though facing domestic lobbying groups opposed to TRIPS, ultimately agreed to its provisions in order to relieve U.S. economic pressures, which it judged to be of greater importance.

When implementing TRIPS, however, India took a very gradual approach. As Robert Bird observes, "India [progressed] toward compliance at the slowest pace possible that [avoided] sanctions" (Bird 2006:22). This pace was characterized by three sets of amendments to India's 1970 Patents Act, all of which brought India's domestic laws into compliance with the TRIPS provisions. Such gradualism, contrary to some analyses, was in fact quite rational given the

economic and political changes introduced by TRIPS compliance. First, price increases on drugs due to patent protections increased the prices of local drugs, a move certain to end India's ability to provide for nearly the nation's entire domestic drug supply (Musungu and Oh 2006: 16-18). Second, product patents prevented Indian manufacturers from reverse engineering pharmaceuticals and developing them through alternate processes. Without reverse engineering, India's generic manufacturing sector could not provide affordable drugs for export to LDCs, nor could it create products as innovative as Cipla's triple-combination therapy Triomune, the first drug of its kind in the world (Musungu and Oh 2006: 18-19). As both measures undermined India's IPR stance to "make patents work for the nation," any approach that limited the effects of these policy changes was warranted in the minds of Indian policymakers.

India's overarching policy approach, then, was one of gradual implementation of TRIPS, what Bird terms the "delay cycle": act only when U.S. pressure is applied and, even then, satisfy only the "bear minimum necessary to avoid economic sanctions" (Bird 2006: 24-26). After failure of the Indian Parliament to enact the president's 1994 ordinance, for example, the United States applied pressure on India to rush its legislative process and enact the first set of amendments to its 1970 legislation. The United States Trade Representative (USTR) placed India on its list of priority watch nations, opened an investigation into India's failure to extend product patents to the pharmaceutical and agricultural fields, and submitted the matter to the WTO Dispute Settlement Body (Bird 2006: 23-24). The sum of these measures led to sanction on India by the body, which set 2 March 1998, as India's deadline for compliance. Amid such pressure, the Indian government still did not amend its legislation until a year later, and even then, the amendment only concerned the mailbox procedure and exclusive marketing rights to patent holders.

The second and third amendments to the Patents Act followed a similar track to the first amendment, taking place only after significant pressure from pharmaceutical companies forced India's hand. In the lead up to the second amendment, pharmaceutical companies requested that the USTR place India on the priority watch list, noting India's continued delay in adopting all TRIPS provisions (Bird 2006: 24-25). Legislation extending patent protection to twenty years was drafted but failed to clear both houses of Parliament. The amendment that was eventually passed in 2002 still fell short of full compliance, especially in the area of product patents, which had yet been included in any piece of legislation. The third amendment attempted to redress

these shortcomings by including a product patents regime. However, to the Pharmaceutical Research and Manufacturers of America (PhRMA), India remained far from compliance; PhRMA was "concerned about a number of late amendments to the bill that may bring India into conflict with its minimum international obligations" (PhRMA 2005). Pharmaceutical company opposition aside, it appears unlikely that India will further amend its IPR regime, settling at a point where its level of compliance is to the satisfaction of United States.

The total effect of India's delay cycle was to create enough room for the Indian government to adhere to TRIPS provisions without compromising its national interests on intellectual property. In striking this balance, it enacted measures that preserved its domestic manufacturing edge. One such measure in the 2005 amendment defined the limits of patentable material by restricting *pharmaceutical substance* to "any new entity involving one or more inventive steps" and *new invention* to "any new invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application" (Ministry of Law and Justice 2005: 2). Such strict definitions give the nation's Patent Office wide latitude in rejecting patent applications it finds guilty of evergreening. The Channai High Court's rejection of Swedish manufacturer Novartis's patent application for Gleevec, a cancer drug, is a case in point. After a year of legal battles, the Court ruled at the end of 2006 that the drug did not constitute a "new and more efficacious version" of its older cancer drug, which was already produced generically in the country (Whalen and Greil 2009; MSF 2006; Mueller 2007: 541-543). Although the decision struck a blow to pharmaceutical companies, it did not motivate countervailing actions from the United States, indicating the generally cooperative light in which Indian IPR actions are viewed.

A second measure permitted Indian manufacturers to continue producing newly patented drugs—and shielded them from patent holder suits—so long as generic production took place before passage of the 2005 amendment and so long as the patent holder was fairly compensated. This measure was in reaction to the mailbox procedure and has been instrumental in securing India's booming generic drug industry. Also supporting India's generics sector was a third measure clarifying instances in which the Indian government or generic firms sought compulsory licenses. More specifically, compulsory licenses were permitted to remedy anti-competitive practices and to export generic drugs to LDCs lacking domestic manufacturing capacity (Musungu and Oh 2006: 22-24). These measures, combined with India's gradual approach to

TRIPS implementation, allowed for flexible policies that enabled the nation to "protect Indian sovereignty in the face of an aggressive foreign power"—a key national interest (Bird 2006: 25).

Brazil: Policy Liberation and Strategic Competition

Much like India, Brazil faced economic pressures from the Western world, especially the United States, to amend its IPR policies. The most famous instance of U.S. economic coercion was the 1987 case launched by the Pharmaceutical Manufacturers Association (PMA) to bring the Brazilian government into compliance with global intellectual property standards. The PMA estimated its losses due to Brazilian disregard for IPRs in the hundreds of millions of dollars and subsequently filed a petition with the USTR (Bird 2006: 9). Under Section 301 of the U.S. Trade Act, the United States sanctioned the nation, increasing import duties on key Brazilian products that amounted to $200 million in trade costs (Bird 2006: 9-10). A year after the imposition of sanctions, the Brazilian government buckled and agreed to initiate changes to its IPR policy.

Under similar economic pressures a decade later, Brazil implemented the full load of TRIPS provisions in a single legislative act. This move significantly hampered its once burgeoning drug manufacturing sector in numerous ways. First, the mailbox provision prevented Brazil from producing new first and second-line ARVs (Coriat, Orsi, and d'Almeida 2006: 1053-1054). Second, non-use of its domestic manufacturing capacity required the government to look abroad for the latest ARVs, thus necessitating ARV imports, whose legality was still undetermined following the Doha Declaration. Third, lack of IPRs governing pharmaceutical products and processes permitted Brazilian industries to reverse engineer innovator compounds, thereby fueling the government and generic sector's ARV production capabilities (Orsi et al. 2003: 122). Patent protection of these goods, therefore, threatened the competitiveness and sustainability of its drug manufacturing sector. The combined effect of these provisions was to drive up ARV prices, jeopardizing the government's ability to subsidize universal ARV distribution to its population. Furthermore, the TRIPS provisions undermined Brazil's bargaining power with pharmaceutical companies, exacerbating the situation.

Brazil's diminished capacity to negotiate ARV price reductions was evident in its 2005 agreement with U.S. manufacturer Abbott Laboratories concerning the ARV drug Kaletra. Initially, Brazil found Abbott unwilling to agree on price reductions suitable to its ARV program's needs. As a result, it considered compulsory licensing the drug to break Abbott's

patent entirely or, at minimum, force price reductions. Rather than relent, the drug manufacturer dug in and even threatened to pull distribution of the drug in Brazil should the government take such action (Coriat, Orsi, and d'Aleida 2006: 1057-1058). The agreement eventually reached between the two parties proved highly disadvantageous to Brazil: use of TRIPS flexibilities was prohibited, and the price of the drug was fixed for the twenty-year patent period. The agreement showed the extent to which quick adoption of the TRIPS provisions had limited Brazil's policy options and bargaining power in IPR matters.

Left with few choices, the Brazilian government undertook a more hostile approach in order to secure its national interests concerning ARVs. Using the TRIPS flexibility of compulsory licensing, the government began threatening the use of compulsory licenses to motivate price reductions from pharmaceutical companies. Initially, such a strategy was rather successful. Between 2001 and 2003, the mere threat of licensing a patented product to a generic or government-run manufacturer led to large price reductions for certain drugs.[2] The strategy's success, however, was short-lived. Further ARV price reductions after 2003 were marginal and halted abruptly in 2005 when Abbott deemed Brazil's licensing threat hollow and, in turn, negotiated an agreement that proved more favorable to the drug company than to the Brazilian population.

Realizing the growing weakness of its strategy, the Brazilian government altered course, issuing its first compulsory license in 2007 for U.S. manufacturer Merck and Co.'s ARV drug Efavirenz. Before the decision to bypass the patent, Brazil was in negotiations with Merck to lower the price of the drug from $1.59 to $0.65 per pill (BBC News 2007). Given the importance of the drug to Brazil's national treatment program—Efavirenz constituted over one-third of ARVs distributed by the government—eventual failure to agree on a price motivated Brazil to license it for generic production (Ford et al. 2007: S26). Following its dispute with Merck, the government rejected U.S. manufacturer Gilead's patent application for Viread in 2008, arguing that the drug was in the public interest and could not be patented (Peer 2008).

Crucial to Brazil's competitive strategy was the credibility of its commitment to muscle concessions from pharmaceutical companies and defy U.S. objections. On one level, this credibility derived from Brazil's overarching commitment to its universal ARV distribution

[2] Seventy-three percent reduction in price for Efavirenz, 56 percent for Lopinavir/Ritonavir, and 74 percent for Nelfinavir (Ford et al. 2007: S24-S25).

program. Orsi et al. suggest that the program "provided unambiguous elements for dealing with key issues in the country's political economy" (Orsi et al. 2003: 131). One key element was the favoritism shown by the government to local drug manufacturers, evidenced by Brazil's history of weak IPRs. On another level, Brazil's resilience to U.S. economic coercion—once a powerful tool for influencing its policy—increased the government's leverage against pharmaceutical companies. In 2001, the United States filed suit against Brazil through the WTO, and over the last several years it has been on the USTR's watch and priority watch lists (Crossette 2001; USTR 2007). Even so, the government remained committed to its ARV distribution policy, thus increasing its bargaining power with pharmaceutical companies fearful that U.S. pressure would be ineffective. Although its 1996 legislation limited its policy options, Brazil has since carved out policy space by pursuing a competitive strategy backed by a credible commitment to compulsory licensing.

Conclusion

India and Brazil's differing approaches to TRIPS implementation demonstrate states' varied responses to U.S. economic coercion and the subsequent policy options that are available to them. India's delay cycle allowed the government to adopt TRIPS provisions in a manner that preserved India's national interests—including its generic drug industry—while satisfying Western demands. Alternatively, Brazil's quick implementation hampered its public health goals, thus necessitating its use of compulsory licensing to liberate its policy decisions from TRIPS restrictions. In both cases, the amount of policy space provided by each country's implementation strategy shaped its dominant approach to TRIPS adherence: cooperation by India and competition by Brazil.

Implementation of TRIPS provisions is generally a complicated and controversial process. Numerous other countries are dealing with pharmaceutical-related IPR issues now and face similar pressures, whether economic or political, from Western nations and pharmaceutical companies. Although India and Brazil present possible strategies for balancing intellectual property laws and public health priorities, their examples are not ideal approaches.

For India, gradual implementation through legislative amendments elicited U.S. objections on multiple occasions. Although India ultimately resisted the tide of American pressure and, as a result, protected its generic pharmaceutical industry, it benefitted from unique

circumstances. First, U.S.-India relations are largely tied to noneconomic matters—nuclear weapons and regional security being the most obvious. Therefore, U.S. pressure on India over TRIPS implementation was more symbolic than substantive; the United States refused to carry out sanctions on par with its late 1980s threats for fear of jeopardizing other issues in the relationship. Second, India's extensive bureaucratic process—tied to its identity as the largest democracy in the world—provided it with political cover against American pressure. As often as the United States complained about India's lagging implementation, it was unable to make more trenchant criticisms for fear of decrying the Indian legislative process itself. Such a criticism would undermine American rhetoric concerning the merits of democratic institutions. Thus, the U.S. position on Indian implementation of TRIPS took an increasingly soft tone, eventually settling on India's 2005 amended laws. Given the unique circumstances in which India found itself, the delay cycle was a reasonable policy approach. For other nations in the developing world, however, the delay cycle is unlikely to take a similar course; many LDCs lack bargaining items—like nuclear weapons or democratic institutions—with which to motivate concessions from the United States.

For Brazil, its use of compulsory licensing, though successful, is not sustainable. Of primary concern are the rising costs of ARV procurement. According to Orsi et al., as of 2003, Brazil spent 62 percent of its total ARV procurement budget on patented drugs (Orsi et al. 2003: 129). This figure will increase as current ARV prices rise and newly invented ARVs with patent protection enter the market. In other words, Brazil's policy of universal ARV access is outpacing its generic pharmaceutical industry, which faces obsolescence due to patent laws that preclude it from copying and distributing new drugs.

Of secondary importance is the Brazilian Health Ministry's long-term response to ARV procurement. In particular, if Brazil's commitment to licensing is ever undermined or foreign nations' ARV exports ever limited, then its current strategy represents nothing more than a "temporary window of opportunity" (Orsi et al. 2003: 129). Compulsory licensing is only successful when states' commitment to obtaining the license is credible in the eyes of pharmaceutical companies. Should Brazil ever back out of the process or lack the resources to complete it, its credibility would be lost, inviting a host of legal challenges from firms, such as Merck and Roche, seeking patent protection for their inventions. Additionally, should new laws or unforeseen circumstances in India or China ever limit their ARV exports to Brazil, then the

Ministry of Health would lack the means to provide universal ARV access to its population. The Brazilian strategy, therefore, provides a temporary solution that few LDCs can emulate, let only sustain.

A Framework for Global Health Policy

Given such limitations, LDCs should pursue a two-track policy focused on the adoption of international IPRs and commercialization of scientific research. At the moment, little attention is paid to the positive effects of IPRs on LDC economies. As much as IPRs incentivize corporate research and innovation, they also spur private sector research in emerging markets. According to Bruce Lehman, "The continuing lack of patent protection for pharmaceutical products makes it very difficult to establish research-based industries in most developing countries" (Lehman 2003).

Upon developing stable research-based industries, LDCs should use international IPRs for their own gain by patenting their inventions in Western nations. Such commercialization would preserve LDCs' scientific advances—and the returns from them–while generating private sector competition without state intervention. Evidence of this approach is found in India's Council for Scientific and Industrial Research (CSIR), where useful inventions are patented in both India and larger markets like the United States (Lehman 2003). Thus, for LDCs, reform of IPRs and engagement in scientific research may curry favor with DCs as well as generate benefits for their own economies.

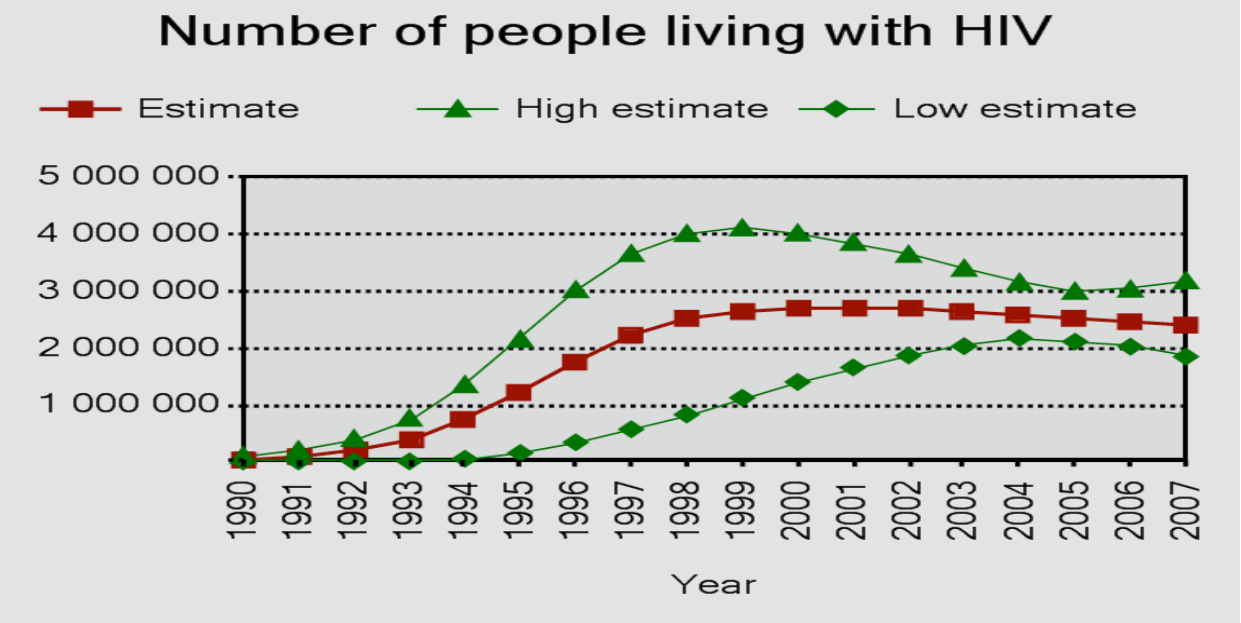
LDCs aside, pharmaceutical companies also play a pivotal role in TRIPS implementation and enforcement. Their efforts have hitherto focused on reporting or challenging LDC actions found in violation of the TRIPS provisions. Their energies, however, should be redirected toward more cooperative ventures with LDCs. The African Comprehensive HIV/AIDS Partnerships (ACHAP) is a case in point. Created in 2000, ACHAP is a public-private partnership between Merck, the Bill and Melinda Gates Foundation, and the government of Botswana to support care, treatment, and prevention for HIV/AIDS in Botswana (Ramiah and Reich 2005: 545). In fact, one of its main activities involves support of Botswana's national ARV program. Through ACHAP, Merck made a financial commitment to provide ARVs to Botswana's population, an approach far different from its dealings with Brazil in 2007. Such a partnership, leveraging the

resources and expertise of the private sector, exemplifies the importance of pharmaceutical companies to the global HIV/AIDS response.

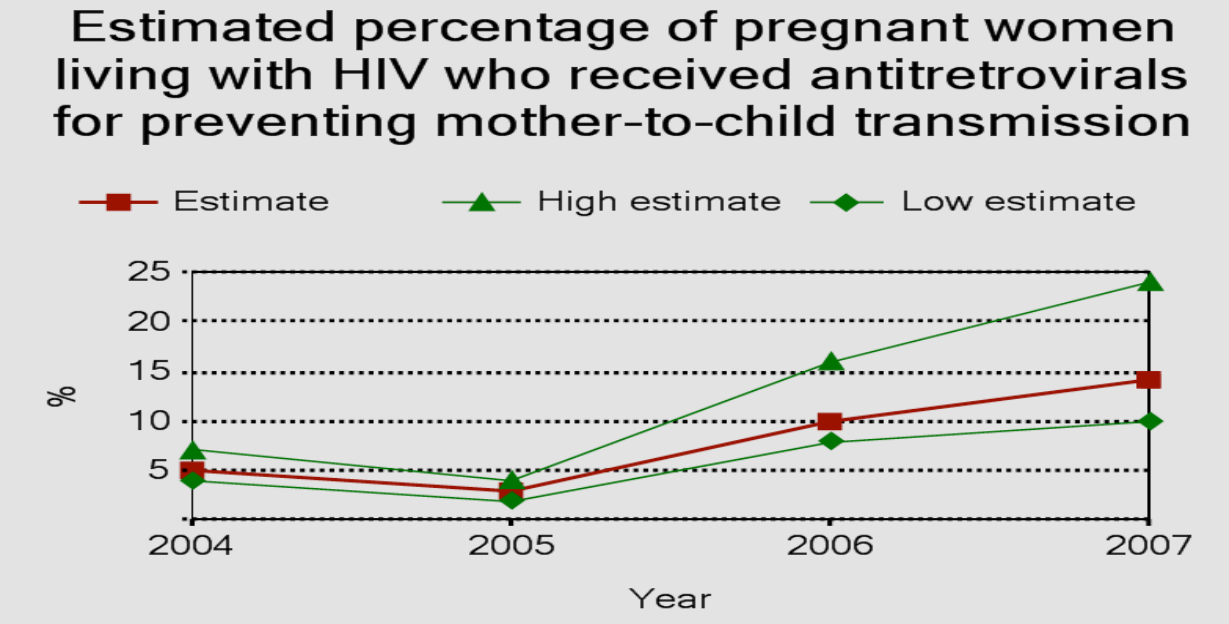
Initially, one would consider the partnership almost entirely parasitic; LDCs receive ARV donations while pharmaceutical companies lose millions in sales. Yet, these companies actually have much to gain from such partnerships. For example, the publicity generated by legal disputes between LDCs and pharmaceutical companies may negatively affect employee morale. Oxfam International concluded as much when—in reference to pharmaceutical companies' resistance to South Africa's production of generic ARVs in 2001—it found that the "issue of access to medicines in poor countries has proved a real reputation risk, threatening investor confidence and employee morale" (Bluestone, Heaton, and Lewis 2002: 10). Scientists developing new ARV treatments, it is argued, care to know that their breakthroughs are aiding populations in underserved regions. Therefore, public-private partnerships are advantageous to pharmaceutical companies from a personnel standpoint: they boost employee morale by linking scientific breakthroughs to philanthropic activities. Joyce Meng, CEO of Givology, observes that such partnerships, by utilizing private firm resources for social objectives, may acquire competitive advantages which, among other things, includes "boosting employee morale" (Meng 2007). As a result, partnerships like ACHAP serve the dual purpose of aiding LDCs' ARV programs and supporting pharmaceutical companies' top talent.

The diverging goals of LDCs and pharmaceutical companies—especially regarding TRIPS implementation and ARVs—oftentimes cloud their judgment on vital public health issues. Thus, the task for policymakers and executives is to identify and exploit areas where synergies exist. For LDCs, that may involve commercialization of scientific research, and for pharmaceutical companies, that may concern public-private partnerships. The examples of India and Brazil demonstrate the limits of economic coercion by Western actors and the lengths to which non-Western states will go to secure their interests. The challenge, therefore, is to fashion policies that can bridge the divide between Western world goals and developing world interests.

APPENDIX 1: HIV/AIDS Disease Burden and ARV Treatment in India

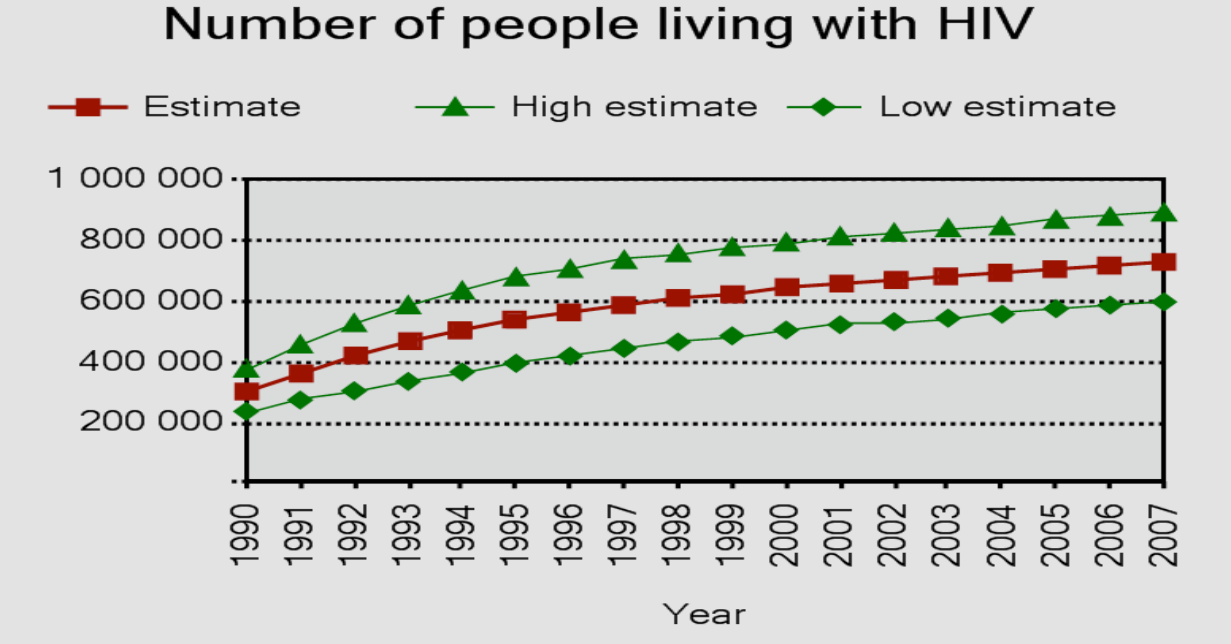


Source: UNAIDS/WHO, *Epidemiological Fact Sheet on HIV/AIDS: India* (Geneva, Switzerland: UNAIDS/WHO, October 2008).

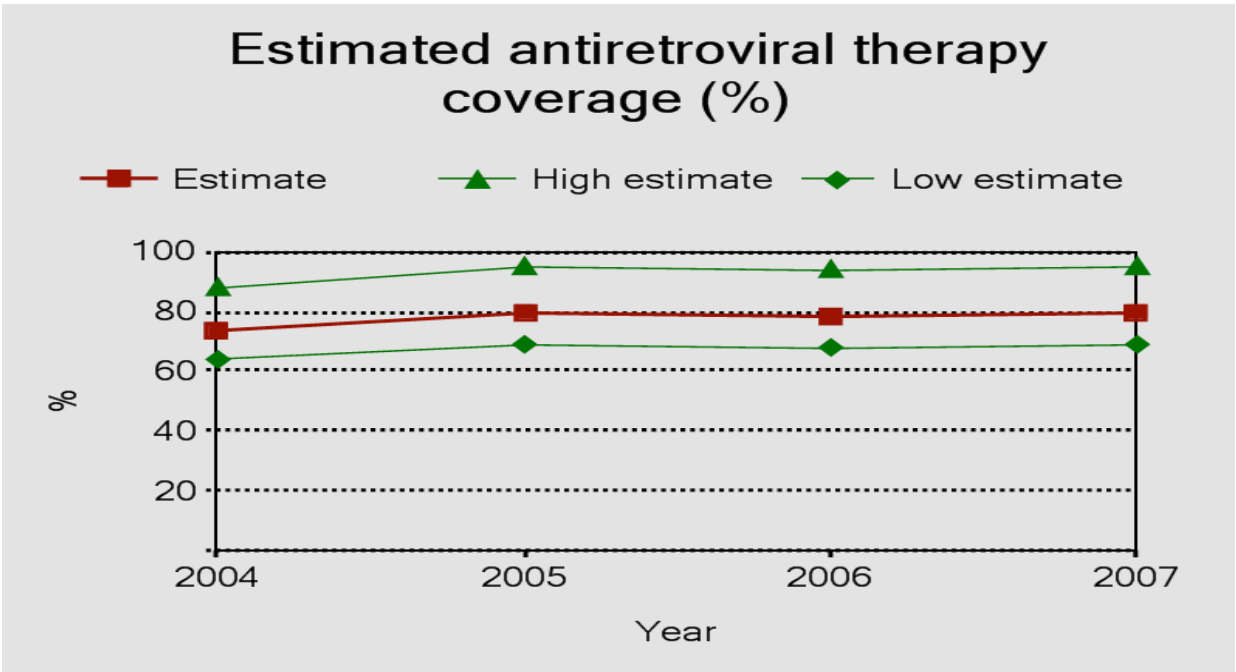


Source: UNAIDS/WHO, *Epidemiological Fact Sheet on HIV/AIDS: India* (Geneva, Switzerland: UNAIDS/WHO, October 2008).

APPENDIX 2: HIV/AIDS Disease Burden and ARV Treatment in Brazil



Source: UNAIDS/WHO, *Epidemiological Fact Sheet on HIV/AIDS: Brazil* (Geneva, Switzerland: UNAIDS/WHO, December 2008).



Source: UNAIDS/WHO, *Epidemiological Fact Sheet on HIV/AIDS: Brazil* (Geneva, Switzerland: UNAIDS/WHO, December 2008).

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